ORIGINAL ARTICLE

Clinical and linguistic validation of the Polish version of VascuQol: a disease-specific quality-of-life questionnaire assessing patients with chronic limb ischemia

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KEY WORDS

health-related quality of life, intermittent claudication, patient-reported outcome measures, peripheral arterial disease, validation studies

ABSTRACT

INTRODUCTION Objective clinical assessments should include patient-reported outcome measures. VascuQol is an established disease-specific questionnaire assessing the quality of life in patients with peripheral artery disease (PAD). Quality-of-life questionnaires require geographical localization and validation.

OBJECTIVES The goal of this study was to validate the Polish version of the VascuQol: a patient-reported health-related quality-of-life (HRQoL) instrument specific for PAD.

PATIENTS AND METHODS The linguistic validation of VascuQol followed Mapi Institute methodology. Clinical validation process compared VascuQol, EQ-5D-3L, and SF-36 questionnaires in 100 patients with both intermittent claudication and critical limb-threatening ischemia. Cronbach α coefficients for reliability, receiver operating characteristic curves for clinical discriminative performance, standardized response means for responsiveness, and Pearson correlations for construct validity were evaluated. Additionally, in a separate cohort of 58 patients with stable disease, the test–retest was characterized with intraclass correlation, Bland–Altman analysis, and Pearson correlation coefficients.

RESULTS VascuQol proved to perform better than SF-36 and EQ-5D-3L. Cronbach α coefficients showed good internal consistency (α values >0.9 for all summary scores). All test–retest Pearson *r* values for VascuQol were above 0.70. The intraclass correlation of absolute agreement consistency exceeded 0.8. The Bland–Altman 95% limits of agreement were between 2.72 and 4.87. There were strong and moderate correlations for total scores in all domains between VascuQol and SF-36, and for most of the domains between VascuQol and EQ-5D-3L.

CONCLUSIONS The Polish version of VascuQol is a sensitive, accurate, and reliable tool for assessing HRQoL in patients with PAD.

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INTRODUCTION Chronic limb ischemia has an adverse effect on the quality of life.[1] Evaluation of the outcomes of peripheral arterial disease (PAD) treatment based on objective clinical parameters does not allow for a reliable assessment of pain discomfort, social and emotional aspects, as well as daily functional status associated with PAD and treatment process.[2] For this reason, objective clinical assessments were extended by patient-reported outcome measures. The most common generic questionnaires, the Medical Outcome Study Short Form-36 (SF-36)[3] and

the EuroQoL-5D (EQ-5D-3L)[1] are not sufficiently sensitive to accurately measure deterioration in the quality of life related to limb ischemia, functional walking impairment, and treatment process. Therefore, specific questionnaires were required and developed. They include, but are not limited to, the Walking Impairment Questionnaire,[4] Claudication Scale questionnaire,[5] Peripheral Artery Questionnaire,[6] PAD Quality of Life Questionnaire,[7] and Intermittent Claudication Questionnaire (ICQ).[8] Some of these instruments were validated for local languages other than English.[9-12]

Although the quality of life in patients with PAD was systematically evaluated in Poland,[13,14] mostly general questionnaires were used. Only recently, the Intermittent Claudication Questionnaire, a PAD-specific health-related quality of life (HRQoL) questionnaire was validated in Polish.[15] We selected another questionnaire specific to HRQoL in PAD, namely, the Vascular Quality of Life Questionnaire (VascuQol), because it covers not only a spectrum of claudication symptoms but also demonstrates good reliability in evaluating patients with CLTI, who frequently present at our center.[16]

Characteristics of the VascuQol The VascuQol consists of 25 questions covering 5 domains: activities, symptoms, pain (physical domains), as well as emotions and social behavior (mental domains). The answer to each question is rated with a 7-point scale, where 1 stands for the worst, and 7, for the best rating. The questionnaire was developed by Mark Morgan, MD, from the Surgical Unit of King's College Hospital in London.[17] The VascuQol questionnaire was used in the BASIL study (Bypass vs Angioplasty in Severe Ischaemia of the Leg)[18] and has afterward been translated and validated in other European countries where high psychometric value and applicability in PAD patients was confirmed.[9,11,19] The linguistic validation of the VascuQol in several languages was carried out using Mapi's methodology.[20] Within 25 years, Mapi has linguistically validated more than 2500 instruments in over 170 languages in a wide range of therapeutic areas. Due to cultural differences between nations, the validation process should include both linguistic and cultural adaptation and clinical efficacy of the questionnaire.

Characteristics of the generic quality-of-life instruments **The SF-36 questionnaire** The SF-36 is the world's most widely used generic questionnaire to assess the quality of life in patients with cardiovascular diseases (including PAD). The instrument consists of 36 items, which evaluate 8 health domains, namely, physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. Each item is encoded and converted to contribute to subscale scores from 0 (worst possible results) to 100 points (best health status). The respective domains can be combined into 2 summary measures, representing physical component summary score (PCS) and mental component summary score (MCS). The SF-36v2 is available as a validated Polish version,[21] which was kindly provided by Medical Outcomes Trust and Quality Metric Incorporated[22] (Hanover, New Hampshire, United States).

The EQ-5D-3L questionnaire The EQ-5D-3L questionnaire is a generic quality of life instrument. It consists of 2 parts. The descriptive part includes 5 questions regarding mobility, self-care, usual activities, pain, and anxiety/depression. They are further graded into levels of severity corresponding to "no problems" (level 1), "some problems" (level 2) and "extreme problems" (level 3). EQ-5D-3L health states, defined by the EQ-5D-3L descriptive system, may be converted to a single index value ranging from 0.59 (values for quality of life worse than death) to 1 (good quality of life status) (EQ Index). The second part includes a visual analog scale (EQ-VAS), on which patients can assess their health on a scale from 0 to 100. EQ-5D-3L has a validated Polish version,[23] which was kindly provided by the EuroQol Research Foundation (Rotterdam, the Netherlands). The Polish value set and index calculator were kindly provided by Dominik Golicki, MD, PhD (Warsaw Medical University, Warsaw, Poland).

In this paper, we refer to questionnaires or tools when speaking about HRQoL evaluation instruments, and to tests when speaking about specific statistical assays.

PATIENTS AND METHODS

Linguistic validation The Polish version of the VascuQol was developed using a standard linguistic validation process developed by Mapi.[20] The conceptual analysis of the original VascuQol was performed with Mark Morgan, the developer of the initial questionnaire. As a result, a summary file explaining the meaning of each item and denoting terms for each concept was provided to the translation team. This analysis allowed consistency of the Polish version with the original. Dual forward translation and single back translation followed by the reviews of a local team leader and Dr. Morgan allowed to develop the Polish linguistic translation text. Then, the resulting translation was examined on 5 patients with lower limb ischemia (face-to-face interviews). Attention was paid to assure equal representation of gender and mixed education (ie, a minimum of 2 participants with less than 15 years of school attendance). Patients were asked to complete the Polish version of the VascuQol and raise any issues with understanding the instructions, items themselves, or response scales. They were asked to paraphrase each sentence in the questionnaire or reformulate it in their own words. The interviewer evaluated the patients' understanding of

TABLE 1 Characteristics of the clinical validation cohort: demographic data, risk factors, comorbidities

Parameter	All patients (n = 100)	CLTI (n = 50)	IC (n = 50)	*P* value[a]
Median age, range	68 (49–99)	69 (55–99)	67 (49–81)	0.051
Male sex, %	83	78	88	0.18
Smoking, %	78	72	82	0.33
Diabetes, %	36	44	30	0.21
Hypertension, %	65	66	64	0.83
Lipid disorders, %	40	44	36	0.41
CHD, previous MI, %	39	42	36	0.54
Kidney disease[b], %	12	14	10	0.54
COPD, %	12	8	16	0.22
TIA/stroke, %	4	6	2	0.31

a Significance for nominal data was assessed by the χ^2 test, and for the numerical data, by the Mann–Whitney test.

b GFR <60 ml/min/1.73 m^2

Abbreviations: CHD, coronary heart disease; CLTI, critical limb-threatening ischemia; COPD, chronic obstructive pulmonary disease; GFR, glomerular filtration rate; IC, intermittent claudication; MI, myocardial infarction; TIA, transient ischemic attack

the concept behind each item ("Were they able to provide the meaning of each item?") and reasons for any difficulties in this respect (ie, inaccurate translation or missing cultural relevance for the concept). Similarily, the interviewer verified the cultural relevance of the translation. Alternative wording was provided as needed. Difficulties and suggestions for all instructions, items, and response categories were summarized in a tabelarized synopsis and analyzed before the final version was produced.

The issues encountered during the process and decisions made to solve them were documented and categorized (as cultural, idiomatic, pragmatic, semantic, and syntactic).

Clinical validation Clinical validation of the Polish version of VascuQol was conducted prospectively in consecutive patients referred for endovascular treatment due to PAD in a single large-volume tertiary angiology center in southern Poland. Patient exclusions were exceptional, not predefined, and concerned only patients refusing participation, not able to attend follow-up visits, or not able to read and fill in the questionnaire in Polish. Patients were evaluated simultaneously using 3 HRQoL tools: validated Polish versions of the EQ-5D-3L and SF-36v2 and the analyzed version of the VascuQol. The questionnaires were administered shortly before treatment and 1 month after revascularization.

An additional sample of patients treated in our center was recruited to determine the test–retest stability of the VascuQol. Patients were in a stable phase of the disease and were tested twice within 4 weeks. Disease stage distribution was similar to the first cohort.

Statistical methods and calculations Descriptive statistics was used. Statistical significance for nominal data was assessed by the χ^2 test, and the Mann–Whitney test was used for numerical data.

For VascuQol internal reliability assessment, Cronbach α coefficients were calculated for each domain and for the total score.

The receiver operating characteristic (ROC) curves and areas under the curve (AUC) were evaluated and compared to determine the ability of the VascuQol and other tools to discriminate between patients with intermittent claudication (IC) and critical limb-threatening ischemia (CLTI) before treatment. DeLong nonparametric method[24] was applied to compare differences between ROC curves.

For the test–retest cohort, intraclass correlations (ICC) and Bland–Altman limits of agreement (LOA) were calculated.

Responsiveness was assessed by evaluating significance of differences between the values for each domain before and after treatment (Wilcoxon signed-rank test). Also, standardized response means (SRMs) were calculated according to Husted et al[25] for each domain of the VascuQol, SF-36, EQ Index, and EQ-VAS, as well as for the ankle–brachial pressure index (ABPI) and clinical presentation according to the Rutherford clinical scale.[26] The SRMs were calculated as the mean difference in score 1 month after endovascular treatment as compared with baseline, divided by the standard deviation of the difference.

Cohen criteria for interpreting effect sizes were applied (small effect size ≥0.2 and <0.5; moderate effect size ≥0.5 and <0.8; large effect size ≥0.8). The construct validity of the VascuQol was tested by a correlation analysis versus the SF-36 subscales, EQ Index, EQ-VAS, and ABPI, using the Pearson correlation coefficient. Statistical analysis was performed using SPSS version 18.0 (SPSS Inc. Chicago, Illinois, United States).

Study population **Linguistic validation** We recruited 5 patients with lower limb ischemia (2 women and 3 men), all native-speaking residents of Poland. They ranged in age from 63 to 78 years old (mean, 70.8 years). All had at least 8 years of education.

Clinical validation Between October 2016 and November 2016, we enrolled 100 consecutive patients with PAD for clinical validation purposes. Fifty patients presented with IC (Rutherford class 3) and 50 with CLTI (Rutherford class 4, n = 19; class 5, n = 18; and class 6, n = 13). Except for the disease stage, there were no significant differences in demographic and clinical characteristics of the patients between the CLTI and IC groups. The characteristics of the study cohort are presented in TABLE 1.

TABLE 2 Characteristics of the test–retest cohort (n = 58): demographic data, risk factors, comorbidities

Rutherford class, median (range)	4 (3–6)
Age, median (range)	70 (38–97)
Male sex, %	71
Smoking, %	50
Diabetes, %	48
Hypertension, %	79
Lipid disorders, %	41
CHD, previous MI, %	52
Kidney disease[a], %	19
COPD, %	5
TIA/stroke, %	9

a GFR <60 ml/min/1.73 m^2

Abbreviations: see TABLE 1

TABLE 3 Cronbach α values for the VascuQol domains in patients with critical limb-threatening ischemia and intermittent claudication

Domain	CLTI		IC	
	Pretest (n = 50)	Posttest (n = 50)	Pretest (n = 50)	Posttest (n = 50)
Activities	0.72	0.93	0.88	0.94
Symptoms	0.60	0.84	0.53	0.87
Pain	0.78	0.90	0.80	0.92
Emotions	0.85	0.95	0.89	0.93
Social	0.78	0.82	0.80	0.84
Total score	0.92	0.98	0.95	0.98

Abbreviations: see TABLE 1

We also enrolled a group of 58 patients to assess the test–retest stability. Their characteristics are presented in TABLE 2.

RESULTS **Linguistic validity** No cultural issues were encountered during the translation process. For all items, the most prevalent problem was syntactic with the use of the preterit equivalent tense in Polish to render the use of the present perfect tense in the original English questionnaire. Of the 25 items, 6 generated difficulties, mostly semantic and syntactic (ie, items 3, 8, 11, 15, 19, and 20). The addition of the adjective "physical" in the response categories of items 3, 8, and 20 ("very great deal of discomfort or distress" to "no discomfort or distress") clarified the meaning of the original and enabled a better understanding by the patients.

The translation of item 8 ("In the last two weeks pins and needles or numbness in my leg [or foot] have caused me ...") was challenging. The Polish version tested on patients (back-translation: "In the last two weeks tingling or going numb of the leg [or foot] caused me...") was not entirely understood as it should have been. Patients kept referring to "stiffness" and not to "numbness," that is, lack of sensation. Therefore, it was decided to change the translation and add the Polish equivalent of "missing sensation." The new version was retested on patients who, this time, understood the intended meaning. The addition of "missing sensation" made the Polish item broader in meaning as it included feelings such as "paralyzed, foreign body, not sensitive to touch, as if not mine."

Item 11 ("In the last two weeks being [or becoming] housebound has been a concern of mine...") was problematic because of 2 challenges: 1) the use of the idiomatic expression "housebound" which requires translation with a periphrasis, i.e., "unable to leave home"; and 2) the juxtaposition of an existing situation (being) with a hypothetical one (becoming), which raised much discussion about the syntax of the Polish version and on how to make it clear and not complicated to respondents. Several translations were tested, and the following option was chosen: "In the last two weeks I worried about that now, or in the future, I may be unable to leave home."

As for item 15 ("In the last two weeks because of the poor circulation to my legs, my ability to take part in social activities has been..."), the issue concerned the phrase "to take part in social activities." It required translation into an equivalent of "to participate in social and public life" for a better understanding by the patients.

The main issue in item 19 ("In the last two weeks problems caused by poor circulation to the legs have made me feel frustrated..") was the use of "frustrated" in the original. The translation team felt that the patients would not easily understand a literal translation. It was decided to use the substantive, "frustration", instead, and to add the term "discouragement" to convey the meaning of a deep chronic sense or a state of insecurity and dissatisfaction arising from being unable to change or achieve something.

Finally, item 5 ("In the last two weeks my legs have felt tired or weak...") was not an issue, but interestingly, all respondents used the term "heavy" to describe their feeling.

Reliability The values of Cronbach α coefficients for the VascuQol summary score were in the range of 0.92 to 0.98 and exceeded 0.7 for most of the VascuQol domains.

For the "symptoms" subscale in the pretest for CLTI and IC groups, the α values were 0.6 and 0.58, respectively. The α coefficients for the "symptoms" domain in the posttest for CLTI and IC groups were 0.84 and 0.87, respectively. The results for all subscales are presented in TABLE 3.

Diagnostic reference Baseline VascuQol scores were significantly lower in the CLTI group, both for all and for each separate domain (TABLE 4). Similarly, the differences were significant in the generic SF-36 and EQ-5D-3L questionnaires (Supplementary material, *Table S1*). The ROC curves and AUCs confirmed a high ability of the VascuQol to discriminate the clinical status of patients

TABLE 4 Mean VascuQol scores before treatment in patients with critical limb--threatening ischemia and intermittent claudication

Domain	CLTI (n = 50)	IC (n = 50)	*P* value[a]
Activities	2.20 (0.80)	3.00 (1.26)	<0.001
Symptoms	2.50 (1.07)	4.00 (1.08)	<0.001
Pain	2.30 (0.90)	3.20 (1.30)	<0.001
Emotions	2.60 (1.08)	4.10 (1.49)	<0.001
Social	2.70 (1.58)	3.70 (1.70)	0.003
Total score	2.40 (0.75)	3.55 (1.18)	<0.001

Data are presented as mean (SD).

a Mann–Whitney test

Abbreviations: see TABLE 1

TABLE 5 Area under the curve values for VascuQol, SF-36, EQ Index, and ankle--brachial pressure index

	AUC	SE	*P* value
VascuQol (total score)	0.802	0.044	<0.001
EQ Index	0.738	0.050	<0.001
EQ-VAS	0.670	0.055	0.004
PCS	0.709	0.054	<0.001
MCS	0.638	0.056	0.02
ABPI	0.600	0.061	0.08

Abbreviations: ABPI, ankle–brachial pressure index; AUC, area under the curve; MCS, mental component summary of SF-36; PCS, physical component summary of SF-36; SE, standard error

TABLE 6 VascuQol intraclass correlation results

Domain	ICC	95% CI		*P* value
		LL	UL	
Activities	0.88	0.80	0.93	<0.001
Symptoms	0.89	0.82	0.94	<0.001
Pain	0.83	0.71	0.90	<0.001
Emotions	0.92	0.86	0.95	<0.001
Social	0.80	0.67	0.88	<0.001
Total score	0.90	0.84	0.94	<0.001

Abbreviations: ICC, intraclass correlations coefficient; LL, lower limit; UL, upper limit

between IC and CLTI. A comparison of the AUC between the questionnaires has shown the highest value for the VascuQol, equal to 0.8. Details are shown in TABLE 5 and in Supplementary material, *Figure S1*.

Test–retest reliability All the test–retest Pearson correlation coefficients for the VascuQol were above 0.70 (Supplementary material, *Table S2*). The ICC of the absolute agreement consistency between the pretest and posttest, based on a 2-way mixed model for all measures, was above 0.8 (TABLE 6). For the entire range of possible answers to the VascuQol questions, the Bland–Altman 95% limits of agreement values were between 2.72 to 4.87. Numerical data are shown in TABLE 7, and the Bland–Altman graphs are available in Supplementary material, *Figures S2–S7*).

Responsiveness Specific changes in the evaluated questionnaires found after treatment are shown in TABLE 8. Additional data are presented in Supplementary material, *Figures S8* and *S9*). While the results obtained before and after treatment have changed, the difference reached significance for all domains only in the VascuQol. The SRMs for the VascuQol in both groups were in the range of 0.61 to 1.1. The SRMs for the total VascuQol score both in CLTI and IC groups were higher than 0.8. Conversely, SRMs for EQ-5D-3L and EQ-VAS were lower than 0.5 in both groups. The SF-36 demonstrated good responsiveness (good for PCS and medium for MCS).

Construct validity The total score of the VascuQol in both groups (CLTI and IC) correlated strongly and moderately with the physical and mental component summary scores in the SF-36 and EQ Index (*r* values in the range of 0.51 to 0.76; *P* <0.001). Strong or moderate correlations were also observed between the VascuQol and SF--36 for pain subscales (*r* values in the range of 0.45 to 0.63; *P* <0.01). Strong correlations were also obtained between physical and mental domains of VascuQol and PCS and MCS components of SF-36, respectively. ABPI correlated poorly with any of the VascuQol domains and generic questionnaires. Details are shown in Supplementary material, *Tables S3–S6*.

DISCUSSION

Evaluation of the effects of treatment based on patient-reported outcome measures is an important part of good clinical practice. Although recent efforts of Rosloniec et al[15] have resulted in the first disease-specific HRQoL instrument for PAD that is validated in Polish, it would be not adequate for patients with CLTI, as they can barely walk.[16] Literature reports and a review of available HRQoLs questionnaires indicated that the VascuQol is a robust tool for the assessment of the quality of life in PAD with a wide spectrum of clinical stages of the disease.[16,17] Therefore, we decided to perform a linguistic and clinical validation of the VascuQol in Polish. The methodology developed by Mapi[20] was used to carry out a linguistic validation of the VascuQol, and a clinical evaluation was done using a previously described methodology for other languages.[9,11,27]

Our analysis showed that the Polish version of VascuQol is adequate to evaluate patient-reported outcomes in PAD in patients undergoing endovascular treatment. The results of the linguistic validation demonstrated that the Polish version of the questionnaire is conceptually equivalent to the original. The Bland–Altman analysis[28] showed repeatability of the questionnaire, demonstrating a good agreement between test and retest results in stable patients with both CLTI and IC. Even though the VascuQol consists of 7 grades that define the whole spectrum of the quality of life, and therefore repeatability is difficult to prove, we found a concordance of test–retest results.

TABLE 7 VascuQol Bland–Altman analysis

Domain	Mean difference	SD of difference	SE of difference	95% CI for mean difference		Limit values for 95% LOA
Activities	−0.05	0.71	0.09	−0.24	0.13	−1.45 to 1.33
Symptoms	0.14	0.81	0.11	−0.07	0.35	−1.46 to 1.73
Pain	−0.02	0.99	0.13	−0.28	0.24	−1.94 to 1.91
Emotions	0.08	0.76	0.10	−0.12	0.28	−1.41 to 1.57
Social	−0.03	0.23	0.16	−0.36	0.29	−2.45 to 2.38
Total score	0.02	0.69	0.09	−0.16	0.21	−1.33 to 1.38

Abbreviations: LOA, Bland–Altman limits of agreement

TABLE 8 Health-related quality of life instruments in domain scores in the study population before and after treatment

	Domain	CLTI					IC				
		Pretest	Posttest	Δ	*P* value[a]	SRM	Pretest	Posttest	Δ	*P* value[a]	SRM
VascuQol	Activities	2.2 (0.8)	3.3 (1.6)	1.1 (1.3)	<0.001	0.86	3.0 (1.2)	4.5 (1.5)	1.5 (1.6)	<0.001	0.94
	Symptoms	2.5 (1.1)	3.9 (1.4)	1.3 (1.5)	<0.001	0.90	4.0 (1.0)	4.8 (1.4)	0.8 (1.1)	<0.001	0.7
	Pain	2.3 (0.9)	3.7 (1.3)	1.4 (1.3)	<0.001	1.1	3.2 (1.3)	4.6 (1.6)	1.4 (1.3)	<0.001	1.0
	Emotions	2.6 (1.1)	3.8 (1.6)	1.2 (1.3)	<0.001	0.9	4.1 (1.50)	4.8 (1.6)	0.7 (1.0)	<0.001	0.69
	Social	2.7 (1.6)	3.8 (1.8)	1.1 (1.5)	<0.001	0.76	3.7 (1.7)	4.7 (1.8)	1.1 (1.8)	<0.001	0.61
	Total score	2.4 (0.7)	3.6 (1.4)	1.2 (1.2)	<0.001	1.0	3.5 (1.2)	4.6 (1.5)	1.1 (1.2)	<0.001	0.93
EQ-5D--3L	EQ index	0.5 (0.2)	0.6 (0.2)	0.1 (0.2)	0.001	0.51	0.64 (0.2)	0.69 (0.2)	0.05 (0.2)	0.104	0.24
	EQ-VAS	44.4 (17.0)	53.1 (17.4)	8.7 (15.5)	0.001	0.49	51.9 (11.6)	60.8 (18.1)	8.9 (16.6)	0.001	0.53
SF-36	PCS	25.3 (13.6)	38.5 (17.7)	13.2 (14.8)	<0.001	0.89	33.4 (11.3)	45.0 (10.6)	11.6 (8.7)	<0.001	1.3
	MCS	36.6 (17.7)	46.3 (17.5)	9.7 (12.1)	<0.001	0.79	45.3 (17.0)	54.4 (12.5)	9.0 (12.6)	<0.001	0.71
	BP	19.6 (16.9)	23.6 (24.0)	24.0 (21.8)	<0.001	1.1	28.8(12.1)	46.4(10.9)	17.6 (10.9)	<0.001	1.6
	SF	33.0 (26.2)	44.8 (23.4)	11.8 (22.0)	0.001	0.53	45.8 (20.1)	54.8 (16.4)	9.0 (18.9)	0.003	0.47
	PF	20.6 (20.0)	34.7 (23.5)	14.1 (18.3)	<0.001	0.76	30.6 (16.4)	40.6 (12.7)	10.0 (13.2)	<0.001	0.75
	RP	22.9 (20.4)	38.2 (24.3)	15.4 (17.7)	<0.001	0.86	31.0 (18.7)	46.0 (15.7)	15.0 (15.5)	<0.001	0.96
	MH	43.4 (16.2)	54.7 (12.8)	11.3 (13.0)	<0.001	0.86	48.1 (17.2)	59.7 (11.2)	11.6 (14.8)	<0.001	0.78
	GH	38.2 (12.6)	37.4 (11.5)	−0.8 (11.5)	0.55	−0.06	43.4 (11.5)	47.1 (12.2)	3.7 (10.2)	0.028	0.36
	VT	34.0 (17.5)	42.9 (14.9)	8.9 (13.1)	<0.001	0.67	37.5 (16.4)	50.0 (11.3)	12.5 (11.8)	<0.001	1.12
	RE	36.0 (26.4)	42.8 (26.5)	6.8 (17.8)	0.002	0.38	50.0 (27.8)	53.0 (21.8)	3.0 (21.0)	0.24	0.14

Data are presented as mean (SD). Δ denotes difference between post- and pretest.

a Wilcoxon signed-rank test

Abbreviations: BP, bodily pain; GH, general health; MH, mental health; PF, physical functioning; RE, role emotional; RP, role physical; SD, standard deviation; SF, social functioning; SRM, standardized response mean; VT, vitality; others, see TABLES 1 and 5

Internal consistency for this instrument was excellent for the summary score and acceptable for almost all domains. The only domain that showed a relatively low α value for the scale items was the "symptoms" domain in pretest (<0.7), but in a posttest assessment, it exceeded the value of 0.8. Nordanstig et al[11] who conducted validation in the Swedish population noted a similar low value for the "symptoms" domain. Traditionally, psychometry scaling assumes all items to be "effect indicators" manifesting the same latent construct with a high correlation structure and internal consistency.[11] Conversely, "causal indicators" (eg, symptoms) are subjective. Therefore, they reveal a weaker correlation structure and lower internal consistency in many cases.

A recent evaluation of the Dutch version of the VascuQol by Conijn et al[29] provided additional information on the questionnaire validity, homogeneity, and factor analysis. Some items were found to perform weak in a clinimetric analysis. Additionally, a 3-factor solution was suggested to reduce score variance. As we also noted that some items performed worse, we planned a similar evaluation for the next cohort of our patients, for the Polish version, and after the validation study.

Nevertheless, we believe that valuation of clinical questionnaires should rely on content validity and clinical usefulness rather than on internal consistency.[11,30] The VascuQol demonstrated satisfactory responsiveness in a number of studies,[17,31] in various populations and language versions.

The reliability of the Polish VascuQol was found to be acceptable by all measures, with the values of ICC above 0.8, according to the criteria defined by Terwee et al.[32] While Heerkens et al[33] recommended values over 0.9 for the monitoring of ongoing

processes, we think that lower ICC in the "pain" and "social" domains could reflect slight changes of disease perception after the first visit in a specialized reference center.

The adequacy of the Polish VascuQol was good. We confirmed a relationship between the HRQoL and severity of symptoms in PAD. The ROC curve for the VascuQol performed better than for generic tools in classification of patients with IC and CLTI. The AUC for the VascuQol was above 0.8, which is considered to be a good indicator of diagnostic value and the highest among the instruments evaluated.[32] Responsiveness is used as an indicator of the instrument's sensitivity to change. It also indicates the magnitude of intervention-related change over time. The responsiveness of the VascuQol was good and excellent according to Cohen criteria, in a wide disease spectrum, which is illustrated by the SRM calculations.[34] No floor and ceiling effects were observed based on the criteria described by Terwee et al.[32] These results allow a conclusion that the VascuQol can be a useful tool to evaluate treatment outcomes and to plan further therapy. Good and moderate correlations confirmed the construct validity for the pain, physical, and mental components between the VascuQol and SF-36. As in previous publications,[9,11,17] ABPI correlated poorly with HRQoL scores. It confirms that objective clinical parameters do not necessarily correspond to the perception of the severity of disease by patients.

We are aware that our validation strategy has limitations. The VascuQol was tested in a population of patients presenting with more advanced disease referred for endovascular treatment (Rutherford clinical grade 3 and higher). Thus, the groups with less severe presentation and those referred for surgical treatment were not included in the validation cohort. However, with an ongoing shift from traditional surgical to hybrid and endovascular treatment strategies,[35] and interest in more symptomatic patients, our study group represents a population for whom the HRQoL seems most clinically useful.

Some authors incorporated the multitrait multimethod matrix analysis in the clinical validation process.[11] However, others did not find any significant additional benefit over methods employed in our study.[9] It is additionally cumbersome and therefore was not performed. Although not a limitation of our study, we find the multipoint scale and a relatively large number of questions in a survey to be time-consuming and quite troublesome, especially for elderly patients. Nordanstig et al[31] showed that it is possible to simplify the VascuQol to 6 questions with a 4-point response scale without loss of its psychometric values. Accordingly, a particular validation strategy would be useful.

In conclusion, our study showed that the Polish version of the VascuQol questionnaire is valid, more sensitive, and more accurate than the generic questionnaires in assessing the quality of life of Polish patients with symptomatic PAD.

SUPPLEMENTARY MATERIAL

Supplementary material is available with the article at www.mp.pl/paim.

ARTICLE INFORMATION

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CONTRIBUTION STATEMENT AB and ŁP conceived the concept for the study. All authors contributed to the design and methodology of the research. CA and JL controlled the process of linguistic validation. All authors were involved in data collection. AB, RP, MK, and ŁP analyzed the data. All authors participated in drafting manuscript but also edited and approved the final version of the manuscript.

CONFLICT OF INTEREST CA and JL are full-time employees of Mapi, Language Services. All other authors declare no potential or existing conflict of interest.

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